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## Pulmonary: Synagis®

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***NOTE: Synagis® must be obtained and billed through our specialty pharmacy vendor for Synagis®, Wilcox Home Infusion. Please see Synagis Prior Authorization/Enrollment Form for instructions.***

**LENGTH OF AUTHORIZATION:** Only one dose (based on recipient weight) will be approved per thirty-day period. Dose is given once monthly between November 1st and March 31st (up to 5 doses depending on gestational age).

**INDICATION:**

Palivizumab is indicated for the prevention of RSV lower respiratory tract disease in selected infants and children with chronic lung disease of prematurity (CLD [formerly called bronchopulmonary dysplasia]) or with a history of preterm birth (< 35 weeks' gestation) or with congenital heart disease.

**CRITERIA FOR APPROVAL:**

- Infants born at 28 weeks of gestation or earlier (i.e., ≤ 28 weeks, 6 days) and under twelve months of age at the start of the RSV season (maximum 5 doses).
- Infants born at 29-32 weeks (i.e., between 29 weeks, 0 days and 31 weeks, 6 days) of gestation and under 6 months of age at the start of the RSV season (maximum 5 doses).
- Infants born at 32-35 weeks (i.e., between 32 weeks, 0 days and 34 weeks, 6 days) of gestation who have at least one of the following risk factors and who have not reached 3 months of age: (dosing continues in the RSV season through the end of the month the infant reaches 3 months old – maximum 3 doses)
  - Infant attends child care
  - One of more siblings (or other child permanently in house) < 5 years of age
- Children under 24 months of age with chronic lung disease of prematurity (bronchopulmonary dysplasia) who have received medical therapy (supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy) within 6 months prior to the start of the RSV season (maximum 5 doses).
- Children under 24 months of age with hemodynamically significant cyanotic or acyanotic heart disease (CHD) (maximum 5 doses):
  - Receiving medication to control congestive heart failure
  - Moderate to severe pulmonary hypertension
  - Have cyanotic heart disease
- Infants born at < 35 weeks (i.e., 34 weeks, 6 days) of gestation and under 12 months of age at the start of the RSV season with either: (maximum 5 doses)
  - Congenital abnormalities of the airways
  - Neuromuscular condition compromising handling of respiratory tract secretions

**EXCLUDED FROM APPROVAL:**

- Infants and children with hemodynamically insignificant heart disease.
- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure.
- Infants with mild cardiomyopathy who are not receiving medical therapy.
- Established RSV disease.

**This drug must be obtained and billed through our specialty pharmacy vendor for Synagis®, Wilcox Home Infusion, and processed through the OVHA POS prescription processing system using NDC values. Under no circumstances will claims processed through the medical benefit be accepted.**

**DOCUMENTATION:**

Document clinically compelling information supporting the use of Synagis on the **Synagis® Prior Authorization/Patient Enrollment Form**.